REMARKS

Reconsideration of this application and reexamination of the claims in view of the amendments and remarks presented herein are respectfully requested. Claims 1-22 and 35-71 have been cancelled; claims 23 and 29-32 have been amended; and new claims 72-100 have been added. Claims 23-34 and 72-100 are pending.

New claims 72-77 find support, for example, in original claims 21 and 22. New claims 78-95 find support, for example, in original claims 21-34. New claims 96-100 find support, for example, in original claims 29, 32, 84, 85, and 87. The recitation of "greater than 80%" in claims 23 and 78 finds support, for example, in paragraphs 070 and 071. No new matter enters by amendment.

Restriction Requirement

Claims 23-30 and 32-34, and new claims 78-85, 87-89, and 96-100 correspond to elected Group II. Of these, claims 23-30, 96, 78-85, 98, and 99 are linking claims, which the Office concluded to be generic to Groups I-IV. Applicants have maintained claim 31 and added new claim 86, which correspond to Group IV; and have maintained claims 72-77 and added new claims 90-95, which correspond to Group III. Applicants request that these claims directed to Groups III and IV be examined in this application upon allowance of the linking claims.

Claim Objections

The Office objected to claims 1 and 38 for failing to spell out the acronyms DC-SIGN and HIV, respectively, at their first occurrence. (Office Action at Item 3.) Applicants have spelled out the acronym DC-SIGN in claim 23, at its first use in the

amended claim set, and have not included HIV in the amended claims. Applicants respectfully request withdrawal of the claim objections.

Claim Rejections Under 35 U.S.C. § 112

The Office rejected claims 23-30, 32-37, and 38-41 under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement. Specifically, though the Office acknowledges that the specification is enabling for the claimed methods as they encompass treating viral infections, the Office contends that the specification does not reasonably provide enablement for preventing such infections. (Office Action at Items 4 and 5.) Applicants submit that this rejection has been rendered moot by the amendment of claims 23-30 and 32-37 to no longer recite "preventing", and by the cancellation of claims 38-41. In making this amendment Applicants do not acquiesce to the Office's position regarding enablement of preventing the recited viral infections. Applicants reserve the right to prosecute claims to methods of preventing in continuation and/or divisional applications.

The Office rejected claims 1, 2, 4-6, 9-20, 23-30 and 32-41 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (Office Action at Item 7.) Applicants respectfully traverse.

As amended, the claims recite "wherein the molecule that specifically binds to DC-SIGN is administered in an amount sufficient to inhibit the binding of the *Flaviviridae* virus effector molecule to the DC-SIGN receptor by greater than 80% to thereby treat the *Flaviviridae* virus infection." Applicants submit that this language, in conjunction

with the disclosure at paragraphs 070 and 071 of the specification, makes the metes and bounds of the claims clear. Accordingly, Applicants respectfully request withdrawal of this rejection.

Claim Rejections Under 35 U.S.C. § 102

The Office rejected claims 1, 2, 4-6, 9-20, 38, 39 and 41 under 35 U.S.C. § 102(a) as allegedly anticipated by Littman *et al.* (U.S. Patent No. 6,391,567 B1, herein, "Littman '567"). (Office Action at Item 7.) According to the Office, "Littman '567 discloses a method for treating HIV infection in humans comprising administering humanized monoclonal antibodies (modulator/blocker) that bind DC-SIGN on dendritic cells. The binding of DC-SIGN prevents HIV gp120 (binding moiety of viral effector molecule) from interacting with DC-SIGN. Also disclosed are antibodies that bind to the viral effector molecule, such as antibodies to gp120." (Office Action at Item 7.) The Office considers that these alleged disclosures of Littman '567 anticipate claims 1, 2, 4-6, 9-20, 38, 39 and 41. This rejection has been rendered moot by cancellation of the rejected claims. Applicants respectfully traverse the basis for the rejection and submit that it does not apply to the claims as amended herein.

To anticipate Applicants' claims, Littman '567 must disclose each and every limitation of the claims. *See Verdegaal Bros v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference."); *see also* M.P.E.P. § 2131. Claims 23 and 78 recite "A method of treating a *Flaviviridae* virus infection of a mammal." Some of the dependent claims recite that "the *Flaviviridae* viral

infection is a Dengue virus infection." (*E.g.*, claims 25 and 80.) Littman '567 does not disclose a method of treating a *Flaviviridae* virus infection of a mammal or that method, wherein the *Flaviviridae* viral infection is a Dengue virus infection. For at least this reason Littman '567 does not disclose every element of the pending claims and does not anticipate the claims. Applicants respectfully submit that this rejection can be withdrawn.

The Office rejected claims 1, 2, 4, 6, 9-17, 38, 39 and 41 under 35 U.S.C. § 102(b) as allegedly anticipated by Littman *et al.* (WO 01/64752 A2). (Office Action at Item 8.) The Office characterizes WO 01/64752 A2 as "disclos[ing] antibodies (modulator/blocker) specific for the antigenic fragment of gp120 (envelope subunit protein of HIV and binding moiety of viral effector molecule) that inhibits DC-SIGN on dendritic cells from interacting with gp120. Also disclosed are methods of treating HIV infection by administering antibodies that bind to gp120, thereby inhibiting binding of gp120 to DC-SIGN. The antibodies can be humanized, monoclonal antibodies." (Office Action at Item 8.) This rejection has been rendered moot by cancellation of the rejected claims. Applicants respectfully traverse the basis for the rejection and submit that it does not apply to the claims as amended herein.

To anticipate Applicants' claims WO 01/64752 A2 must disclose each and every limitation of the claims. *See Verdegaal Bros v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference."); *see also* M.P.E.P. § 2131. Claims 23 and 78 recite "A method of treating a *Flaviviridae* virus infection of a mammal." Some of the dependent claims recite that "the *Flaviviridae* viral

infection is a Dengue virus infection." (*E.g.*, claims 25 and 80.) WO 01/64752 A2 does not disclose a method of treating a *Flaviviridae* virus infection of a mammal or that method, wherein the *Flaviviridae* viral infection is a Dengue virus infection. For at least this reason WO 01/64752 A2 does not disclose every element of the pending claims and does not anticipate the claims. Applicants respectfully submit that this rejection can be withdrawn.

The Office rejected claims 1, 2, 4, 5, 9-12, 15-18, 38, 39 and 41 under 35 U.S.C. § 102(b) as allegedly anticipated by Figdor *et al.* (EP 1046651 A1, herein, "Figdor"). (Office Action at Item 9.) According to the Office, "Figdor discloses a method for treating HIV infection in humans comprising administering humanized monoclonal antibodies (modulator/blocker) that bind DC-SIGN on dendritic cells. The binding of DC-SIGN prevents HIV gp120 (binding moiety of viral effector molecule) from interacting with DC-SIGN (Page 4, [0040], page 5, [0046] and page 7, [0070]-[0071])." (Office Action at Item 9.) This rejection has been rendered moot by cancellation of the rejected claims. Applicants respectfully traverse the basis for the rejection and submit that it does not apply to the claims as amended herein.

To anticipate Applicants' claims Figdor must disclose each and every limitation of the claims. *See Verdegaal Bros v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference."); *see also* M.P.E.P. § 2131. Claims 23 and 78 recite "A method of treating a *Flaviviridae* virus infection of a mammal." Some of the dependent claims recite that "the *Flaviviridae* viral infection is a Dengue virus infection." (*E.g.*, claims 25 and 80.) Figdor does not disclose a method of

treating a *Flaviviridae* virus infection of a mammal or that method, wherein the *Flaviviridae* viral infection is a Dengue virus infection. For at least this reason Figdor does not disclose every element of the pending claims and does not anticipate the claims. Applicants respectfully submit that this rejection can be withdrawn.

The Office rejected claims 1, 2, 4, 6, 9-16, 19, 20, 23, 25-30, 32-33, 36 and 37 under 35 U.S.C. § 102(b) as allegedly anticipated by Brandriss *et al.* (*J. Gen. Virology*, 1986, 67:229-234, herein, "Brandriss"). (Office Action at Item 10.) According to the Office, "Brandriss discloses monoclonal antibodies against the E glycoprotein of Dengue virus administered to mice prior to and subsequent to challenge with Dengue virus (page 230, last paragraph and Table 1). While Brandriss does not disclose the DC-SIGN blocker activity of the antibody to Dengue E glycoprotein, the act of administering the antibody to mice reads on the claimed method of treating a disease of a mammal by administering a DC-SIGN blocker. Although the antibody is not called a 'DC-SIGN blocker', the antibody's identity remains the same as that claimed by Applicant[s]. Brandriss' antibody binds to Dengue glycoprotein E and inherently affects the binding of glycoprotein E with DC-SIGN on the cells of the mice." (Office Action at Item 10.) On the basis of this alleged disclosure of Brandriss, the Office concluded that Brandriss anticipates the claims. This rejection has been rendered moot by cancellation of the rejected claims. Applicants respectfully traverse the basis for the rejection and submit that it does not apply to the claims as amended herein.

To anticipate Applicants' claims Brandriss must disclose each and every limitation of the claims. *See Verdegaal Bros v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth

in the claim is found either expressly or inherently in a single prior art reference."); *see also* M.P.E.P. § 2131. The pending claims recite or depend from claims that recite "administering to the mammal a molecule that specifically binds to DC-SIGN." Brandriss does not disclose a method comprising this limitation. Instead, the methods of Brandriss comprise administering a molecule that binds to Dengue glycoprotein E, to in turn affect the binding of glycoprotein E with DC-SIGN. For at least this reason Brandriss does not disclose every element of the pending claims and does not anticipate the claims. Applicants respectfully submit that this rejection can be withdrawn.

Claim Rejections Under 35 U.S.C. § 103

The Office rejected claims 24 and 34 under 35 U.S.C. § 103(a), as allegedly obvious over Brandriss, as applied above, and further in view of Hoogenboom *et al.* (US Patent 5,565,332, herein, "Hoogenboom"). Claims 24 and 34 recite "wherein the mammal is a human," and claim 34 further recites "and the monoclonal antibody is humanized." (Office Action at Item 11.) The Office acknowledges that "Brandriss does not teach a humanized antibody to be administered to humans to treat Dengue virus infection." (Office Action at Item 11.) However, the Office contends that it would have been obvious to combine the alleged teaching of Hoogenboom, that humanized antibodies have been made to several viruses, with the alleged teaching of Brandriss, to arrive at the invention of claims 24 and 34. Applicants respectfully traverse.

The Office bears the initial burden of establishing a *prima facie* case that the claims in a patent application are obvious. M.P.E.P. 2142. Absent such a showing,

Applicants are under no obligation to submit evidence of nonobviousness, and a rejection for obviousness in improper. *See* M.P.E.P. 2142.

To establish *prime facie* obviousness, the Office must make each of three showings. *Id.* First, there must be a suggestion or motivation, either in the reference or references relied on by the Office, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference teachings so as to arrive at the claims under examination. *Id.* Second, one of skill in the art must have had a reasonable expectation of success in making the modification or combination. *Id.* And finally, the prior art reference or references, when modified or combined, must teach or suggest every limitation in the claims. *Id.*

Claims 24 and 34, as they depend from claim 23, recite "administering to the mammal a molecule that specifically binds to DC-SIGN." As described above, in reference to the anticipation rejection over Brandriss, Brandriss does not disclose a method comprising this limitation. Instead, the methods of Brandriss comprise administering a molecule that binds to Dengue glycoprotein E, to in turn affect the binding of glycoprotein E with DC-SIGN. Nothing in Hoogenboom remedies this deficiency of Brandriss. Even if, for the sake of argument only, one of skill in the art would have been motivated to combine Brandriss with Hoogenboom, and expected success in doing so, that combination would still only result in a humanized antibody that binds Dengue glycoprotein E. Such a molecule is separate and distinct from a molecule that specifically binds to DC-SIGN, as recited by Applicants' claims. For at least this reason Brandriss in combination with Hoogenboom does not render claims 24 and 34 obvious. Applicants respectfully submit that this rejection can be withdrawn.

Double Patenting

The Office provisionally rejected claims 1, 2, 9-14, 38, 39 and 41 under 35 U.S.C. § 101 as claiming the same invention as that of claims 1, 2, 9-14, 39, 41 and 42 of copending Application No. 10/700,507. This rejection has been rendered moot by cancellation of the rejected claims herein. None of the pending claims claim the same invention as any claim in Application No. 10/700,507. Accordingly, this rejection can be withdrawn.

"Prior Art" Made of Record

The Office stated that "The prior art made of record and not relied upon is considered pertinent to applicant's disclosure." (Office Action at Item 13.) The Office then stated that "Tassaneetrithep *et al.* (*J. Exper. Med.* 2003, 197(7):823-829) discloses that DC-SIGN (also known as CD209) mediates Dengue virus infection of human dendritic cells and that anti-DC-SIGN antibodies may be considered for designing therapies that block dengue infection at the entry (envelope) level (abstract and page 828)." (Office Action at Item 13.) Applicants note that Tassaneetrithep is in fact not prior art to the instant application. As stated in the first paragraph of the application, "Applicants claim the right to priority under 35 U.S.C. § 119(e), based on Provisional Patent Application Nos. 60/423,582, filed November 5, 2002, and 60/425,246, filed November 12, 2002." Thus, the effective filing date of the instant application is earlier than the publication date of Tassaneetrithep.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 28, 2005

By: _____
Kenneth J. Meyers
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